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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,585	09/29/2003	Daniel J. Cook	14/1452US(1)	5402
22822 7590 03/24/2008 LEWIS, RICE & FINGERSH, LC ATTN: BOX IP DEPT. 500 NORTH BROADWAY SUITE 2000 ST LOUIS, MO 63102				
EXAMINER ERIZO, DARWIN P				
ART UNIT 3773		PAPER NUMBER		
NOTIFICATION DATE 03/24/2008		DELIVERY MODE ELECTRONIC		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

IPDEPT@LEWISRICE.COM  
KDAMMAN@LEWISRICE.COM

### Office Action Summary

**Application No.**

10/674,585

**Applicant(s)**

COOK, DANIEL J.

**Examiner**

Darwin P. Erezzo

**Art Unit**

3773

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 17 December 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The applicant's amendments filed on 12/17/2007 has been entered into the application.

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-9 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Human beings and/or human anatomy are not statutory subject matter and as such cannot be positively set forth as an element(s) of a claimed combination. In Claims 1 and 5, "...a positioning shield surrounding a patient's laryngeal opening..." should read (e.g. --a positioning shield adapted to surround a patient's laryngeal opening--).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
6. Claims 1, 2, 4, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,771,889 to Pagan in view of US 5,653,229 to Greenberg.

(claim 1) Pagan discloses a device comprising a laryngeal mask **14** including a positioning shield **20** that is adapted to surround a patient's laryngeal opening; and a respiratory tube **1** having a circular cross section; and an adapter **10**.

Pagan is silent with regards to device having a respiratory tube with an elliptical cross-section and an adapter for use with an elliptical respiratory tube, the adapter including a body having a first end, a second end and a passage therethrough; wherein said first end has an elliptical cross-section sized to connect internally to said respiratory tube, and said second end has a cross-section that differs from the cross-section of the first end; and wherein the cross-section of the ends are perpendicular to the longitudinal axis of the body.

However, the use of an elliptical respiratory tube in medical devices that are inserted into a patient's trachea is well known in the art. Greenberg discloses an oro-pharyngeal mask that is inserted into the patient's trachea, and a respiratory tube having an elliptical cross section (Fig. 2). This helps with insertion into the trachea because the trachea has an elliptical/oval shape. Greenberg also discloses the device having an adapter **20** that has a transition from the elliptical shape of the respiratory tube to a circular shape for connection with an anesthesia machine (col. 3, ll. 22-32). Greenberg further discloses that the adapter can be integral with the respiratory tube

(col. 3, ll. 23-24) or formed of interconnecting parts (col. 3, ll. 32-36). Greenberg is silent with regards to the interconnecting adapter including a body having an elliptical cross-section sized to connect internally to said respiratory tube.

One of ordinary skill in the art at the time the invention was made would have found it obvious to modify the respiratory tube of Pagan to include an elliptical cross-section, as disclosed by Greenberg, because it would better conform to the dimension of the trachea and would make it easier to insert the device into the trachea. It would also be obvious to one of ordinary skill in the art to modify the adapter of Pagan to include an elliptical first end in order to fit into the modified elliptical respiratory tube. Furthermore, a friction fitting connection is a known form of "interconnecting parts" and would be obvious to one of ordinary skill in the art.

(claim 2) The second end of the modified adapter of Pagan has a circular cross-section for attachment of tubing.

(claim 4) The modified has a wall member, as shown in Fig. 1.

(claim 8) The modified adapter of Pagan will have a transition from an elliptical cross-section to a circular cross-section.

(claim 9) The second end of the adapter is used to connect to an anesthesia circuit or a ventilator circuit (col. 1, ll. 6-8).

7. Claims 3 and 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pagan in view of Greenberg, as applied to the rejections above, and in further view of US 5,024,220 to Holmgren et al.

(claims 3 and 5) The above combination of Pagan/Greenberg discloses all the limitations of the claimed invention, as cited in the rejections to claims 1 and 4 above, but is silent with regards to the first end of the adapter having a raised rib. However, the use of ribs in an adapter is well known in the art, as shown in Fig. 4 of Holmgreen. The ribs help prevent the attached tube from sliding off. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the modified adapter of Pagan to include ribs because it would help prevent the respiratory tube from sliding off.

(claim 6) The second end of the adapter is used to connect to an anesthesia circuit or a ventilator circuit (col. 1, ll. 6-8).

(claim 7) The modified adapter of Pagan will have a transition from an elliptical cross-section to a circular cross-section.

### ***Response to Arguments***

8. After further consideration, the applicant's amendments have overcome the rejections under the Galleher ('088). However, the amendment has necessitated a new grounds of rejections, as provided above. The Pagan reference discloses a laryngeal mask having a positioning shield and the Greenberg reference is used as a teaching reference for the respiratory tube having an elliptical cross-section.

***Conclusion***

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erez whose telephone number is (571)272-4695. The examiner can normally be reached on M-F (8:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Darwin P. Erezol/  
Primary Examiner, Art Unit 3773